



K093512

5. 510(K) SUMMARY

NOV 20 2009

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| Date prepared | November 5, 2009 |
| Name | SenoRx, Inc. 3 Morgan Irvine, CA 92618 T. 949.362.4800; F. 949.362.0300 |
| Contact person | Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300 |
| Device name | EnCor Breast Biopsy System |
| Common name | Biopsy device |
| Classification name | Gastroenterology-urology biopsy instrument |
| Classification regulation | 21 CFR 876.1075 KNW |
| Predicate devices | K040842 (4/30/2004); K003297 (1/18/2001); K030472 (10/9/2003); K051158 (5/16/2005) |
| Description | Modify indications for use to add for use with palpable abnormalities. Device already cleared for imaged abnormalities. The new indication matches predicate device. |
| Indications for use | <p>The EnCor Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.</p> <ul style="list-style-type: none">• It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.• It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. <p>The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.</p> <p>In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the EnCor Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the</p> |

sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Summary of substantial
equivalence

The EnCor Breast Biopsy System with its 7 and 10-Gauge biopsy probes has the following similarities with the predicate devices: same intended use; same design; same patient contacting materials; same operating principle; and same technological characteristics.

Therefore, the EnCor Breast Biopsy System with its 7 and 10-Gauge probes has the same capability of partial removal of palpable masses as does using either of the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

NOV 20 2009

SenoRx, Inc.
% Mr. Eben Gordon
Vice President, Regulatory Affairs &
Quality Assurance
3 Morgan
Irvine, California 92618

Re: K093512
Trade/Device Name: EnCor Breast Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: November 12, 2009
Received: November 13, 2009

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____ EnCor Breast Biopsy System _____

Indications for Use:

The EnCor Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the EnCor Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use X

AND/OR

Over the Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nail KP dyle for rxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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